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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/672,586	09/26/2003	John D. Puskas	16294-0137 (52433-292707)	8660
7590 07/14/2006			EXAMINER	
JAMES G. TAUSCHE 5231 POWERS FERRY ROAD ATLANTA, GA 30327			MULLEN, KRISTEN DROESCH	
			ART UNIT	PAPER NUMBER
			3766	

DATE MAILED: 07/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/672,586	Applicant(s) PUSKAS, JOHN D.	
	Examiner Kristen Mullen	Art Unit 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 5/30/06 (IDS), 4/21/06 (Response, IDS).
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 31-44, 46-59, 131-144, 147-150, 155, 156 and 185 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 46-59, 131-144, 149, 150, 155 and 156 is/are allowed.
- 6) ☒ Claim(s) 31-44, 147, 148 and 185 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 9/26/03 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>4/21/06, 5/30/06</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Information Disclosure Statement***

1. Applicant filed a "Declaration/Clarification of John Puskas, MD" in the information disclosure statement filed 4/21/06. It is unclear if applicant intended for this document to serve as an affidavit/declaration under 37 CFR 1.132. The examiner has not treated it as an affidavit/declaration under 37 CFR 1.132.
2. The references cited by applicants in the information disclosure statements filed 4/21/06 and 5/30/06 have been made of record. The examiner has considered the voluminous references to the best of her ability.
3. The information disclosure statements do not appear to comply with the guidelines set forth in MPEP 2004 regarding both the number of references cited and the elimination of clearly irrelevant art and marginally cumulative information. However, compliance with these guidelines is not mandatory. Furthermore, 37 CFR 1.97 and 1.98 do not require that the information be material; rather, they allow for submission of information regardless of its pertinence to the claimed invention. Also, there is no requirement to explain the materiality of the submitted references.

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4. However, burying of a clearly relevant reference in a long list of citations may not comply with applicant's duty of disclosure. Applicant is advised that the MPEP states the following with respect to large information disclosure statements:

Although a concise explanation of the relevance of information is not required for English language information, applicants are encouraged to provide a concise explanation of why the English-language information is being submitted. Concise explanations (especially those that point out the relevant pages and lines) are helpful to the Office, particularly where documents are lengthy and complex and applicant is aware of a section that is highly relevant to patentability or where a large number of documents are submitted and applicant is aware that one or more is highly relevant to patentability. MPEP § 609.04(a)(III).

This statement is in accord with dicta from *Molins PLC v. Textron, Inc.*, 48 F.3d 1172 (Fed. Cir. 1995), stating that forcing the Examiner to find "a needle in a haystack" is "probative of bad faith." *Id.* at 1888. This case presented a situation where the disclosure was in excess of 700 pages and contained more than fifty references. *Id.* 1888.

5. The MPEP provides more support for this position. In a subsection entitled "Aids to Compliance With Duty of Disclosure," item thirteen states:

It is desirable to avoid the submission of long lists of documents if it can be avoided. Eliminate clearly irrelevant information and marginally pertinent cumulative information. If a long list is submitted, highlight those documents which have been specifically brought to Applicant's attention and/or are known to be of the most significance. See *Penn Yan Boats, Inc. v. Sea Lark Boats, Inc.*, 359 F.Supp 948 (S.D. Fla. 1972) aff'd 479 F.2d 1338 (5<sup>th</sup> Cir 1974). MPEP § 2004.

6. Therefore, it is recommended that if any information that has been cited by applicants in the above referenced information disclosure statements is known to be material for patentability as defined by 37 CFR 1.56, Applicant should present a concise statement as to the relevance of that/those particular documents therein cited.

*Claim Rejections - 35 USC § 102*

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 31-33, 35-41, 44, 147-148 and 185 are rejected under 35 U.S.C. 102(e) as being anticipated by Hill et al. (RE 38,705).

The Hill reference qualifies as prior art because it claims priority as a continuation-in-part to an application filed April 30, 1996, which provides an enabling disclosure of the subject matter relied upon for this rejection.

Regarding claim 31 and 185, Hill shows inserting an electrode (102, 104, 106, 108, 122, 124, 126, 142, 144, 152, 154, 156, 158, 162, 164, 166) into the jugular vein of a patient and actuating the electrode to create an electrical field effective to stimulate the vagus nerve to achieve controlled asystole (Abs. Col. 7, lines 31-Col. 8, line 64; Figs. 7-15).

Regarding claims 32 and 147, Hill further shows inserting a first electrode (102, 122, 142, 152, 162) into the jugular vein of said patient; and inserting a second electrode (104, 106, 108, 124, 126, 144, 154, 156, 158, 164, 166) into the jugular vein of said patient in spaced apart relation to said first electrode; and actuating the electrode to create an electrical field comprises the step of actuating at least one of said first and second electrodes to create an electrical field (Figs. 7-15).

With respect to claims 33, 35 and 148, Hill further shows the second electrodes is located approximately 1 cm from the first electrode and actuating one or both of the electrodes in unipolar (Col. 7, lines 42-47)

Regarding claims 36-37 and 41, Hill shows stimulating the vagus nerve for between 5 and 90 seconds, and 5 and 15 seconds and having a duration of about 0.4 msec (Col. 6, lines 10-19).

With respect to claims 38-40, Hill shows applying an impulse at a frequency of between 1 HZ and 500 Hz, between 20 HZ and 80Hz, and about 40Hz (Col. 6, lines 10-19).

Regarding claim 44, Hill shows the vagus nerve stimulation is performed during off-pump coronary artery bypass.

With respect to claim 147, Hill shows

***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hill et al. (RE 38,705) as applied to claim 32 above and in further view of Taylor et al. (5,913,876)

Although Hill fails to explicitly show that creating an electrical field comprising actuating both of the first and second electrode (i.e. bipolar stimulation), attention is directed to Taylor who teaches that bipolar stimulation is more efficient than unipolar vagal stimulation (Col. 11, lines 9-13).

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It would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the method of Hill to include creating an electrical field comprising actuating both of the first and second electrode since Taylor teaches that bipolar stimulation is more efficient than unipolar stimulation.

11. Claims 42-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hill et al. (RE 38,705).

Hill discloses the claimed invention except for applying an electrical impulse with amplitude of 1 to 40 V or 2 to 6 V. It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to modify the electrical impulse amplitude as taught by Hill with an electrical impulse having an amplitude of 1 to 40 V or 2 to 6 V, since applicant has not disclosed that this amplitude of electrical impulse provides any criticality and /or unexpected results and it appears that the invention would perform equally well with the electrical impulse amplitude of 10 to 100 mA taught by Hill for stimulating the vagus nerve to achieve controlled asystole.

#### ***Response to Arguments***

12. Applicant's arguments with respect to claims 31-44, and 147-148 have been considered but are moot in view of the new ground(s) of rejection.

#### ***Allowable Subject Matter***

13. Claims 46-59, 131-144, 149-150 and 155-156 are allowed.

#### ***Conclusion***

14. Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 4/21/06 prompted the new ground(s) of rejection presented



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in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

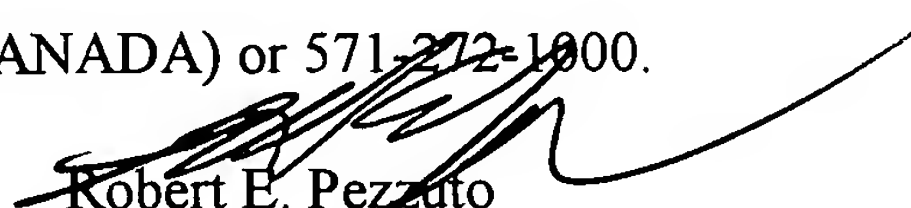

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen Mullen whose telephone number is (571) 272-4944. The examiner can normally be reached on M-F, 10:30 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-212-1000.



Robert E. Pezzuto  
Supervisory Patent Examiner  
Art Unit 3766

kdm